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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/258,132 02/26/99 GOELET

P 04990.0007.U

EXAMINER

HM22/0831

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ART UNIT

PAPER NUMBER

1655

DATE MAILED:

08/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/258,132

Applicant(s)

Goelet et al.

Examiner

Lisa Athur

Group Art Unit
1655



☒ Responsive to communication(s) filed on Dec 3, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 60-63 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 60-63 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. This application is a continuation of application 07/664,837 which is now U.S. Patent 5,888,819. Claims 1-59 have been canceled and claims 1-63 have been added. Applicant should note that claim 64 of the preliminary amendment has been renumbered as claim 63 due the misnumbering of the claims in the amendment.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 60-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 60-63 are directed to a method in which either one or more unique oligonucleotide primers are attached to a unique affinity moiety which specifically binds to a discrete position on a solid support or a plurality of unique oligonucleotide primers are attached to discrete positions of a solid support and then the target nucleic acid is added and to form a duplex and extension occurs on the immobilized primers. Additionally, claim 63 further includes a step of sorting the extended primers by affinity capture. None of these concepts have been disclosed in the specification. The preliminary amendment point to page 27, lines 12-24, pages 29 and 30 and page 31, lines 25-35 as providing support for these the new claims. However, upon thorough

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review of specification, particularly the cited portions of the specification, the claimed subject matter was found to be insufficiently described to reasonably convey to the skilled artisan that applicant was in possession of the claimed invention at the time of filing. While the specification described attaching one or more affinity moieties to the primers to permit affinity separation (page 27, lines 12-24), and described the affinity moiety as being a complementary nucleic acid sequence (page 27, lines 19-24), the specification does not describe the concept of attaching the primers or the affinity moieties to discrete positions on a solid support. From the specification it is clear that the intent of the immobilization on the solid support and the attachment of affinity moieties is to achieve separation of the extended primer from the unincorporated labeled terminators. Page 29, line 31 through page 30, line 3, teach the concept of simultaneous analysis of more than one oligonucleotide using more than one affinity group. This teaching, however, is not equivalent to the attachment of a plurality of oligonucleotide primers or a plurality of affinity moieties to "discrete positions" of a solid support. This concept of "discrete positions" has not been described in the specification and does not appear to have been part of the original inventive concept. The claims, as written, read on methods using oligonucleotide array technology which was not described in the specification. The specification only teaches the general concept that multiple oligonucleotide primers each with a different affinity moiety can be used to detect multiple target nucleotides. However, the specification does not teach the more complex concept of specifically arranging the oligonucleotides and/or affinity moieties to discrete positions on a solid support and determining the identity of a target nucleotide by determining its position on a

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solid support. Claim 63 is particularly unsupported by the specification because the specification contains no description of sorting the extended primers by affinity capture and then determining the identity and location of the terminator to determine the identity of the bases at a plurality of sites. These concepts are unobvious extensions of the teachings that a different affinity moiety can be used to capture a plurality of different primers because the teachings contain no reference using the affinity moieties to sort the primers or to capture the primers at specific locations on a solid support as a means for identification of the target bases. Therefore, for the reasons, given above, the claims introduce new matter into the specification.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 60-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 60-63 are indefinite over the recitation of the terms “discrete position” and “defined positions” because the terms make the claims unclear as to whether the each primer or affinity moiety is attached at a specific and unique location on a solid support or whether a discrete position includes a spot in a dot blot, for example, as shown in figure 8, wherein the dot blot contains the entire reaction mixture.

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6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 60-63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-56 of U.S. Patent No. 6,004,744.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain overlapping subject matter. Claims 60-63 encompass embodiments using one immobilized oligonucleotide primer for the single base extension reaction to identify a specific nucleotide. Claims 13-56 of patent 6,004,744 are also drawn to methods using an immobilized primer for the single base extension reaction. The recitation in claims 60-63 that the primer is immobilized in a "discrete" or "defined" position is unclear (see rejection made above under 35 U.S.C. 112, second paragraph), but does not differentiate the instantly claimed methods from that of patent 6,004,744, particularly for the embodiments wherein only one primer is immobilized.

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8. Claims 60-63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-48 of U.S. Patent No. 5,888,819 in view of Dattagupta et al.

The claims of patent 5,888,819 are drawn to a method for determining a the base at a specific position in a nucleic acid by performing a single base primer extension reaction in the presence of labeled terminators and the absence of dNTPs. The claims do not include a limitation that the primers are immobilized on a solid support. However, Dattagupta et al. teach that primer extension reactions can be performed on immobilized primers with the advantage being that unincorporated nucleotides can be easily separated from the extension product. Therefore, it would have been prima facie obvious to one of ordinary skill to have modified the method of the claims in patent 5,888,819 to be immobilized as taught by Dattagupta et al. In order to achieve the expected benefit of more easily and quickly removing unincorporated nucleotides from the primer extension reaction. Applicant should note that this rejection is directed to the embodiments of the claims limited to use of a single primer.

9. Claims 60-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-59 of copending Application No. 09/258,132 in view of Dattagupta et al.

The claims of application 09/258,132 are drawn to a method for determining a the base at a specific position in a nucleic acid by performing a single base primer extension reaction in the

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presence of labeled terminators. The claims do not include a limitation that the primers are immobilized on a solid support. However, Dattagupta et al. teach that primer extension reactions can be performed on immobilized primers with the advantage being that unincorporated nucleotides can be easily separated from the extension product. Therefore, it would have been prima facie obvious to one of ordinary skill to have modified the method of the claims in application 09/258,132 to be immobilized as taught by Dattagupta et al. In order to achieve the expected benefit of more easily and quickly removing unincorporated nucleotides from the primer extension reaction. Applicant should note that this rejection is directed to the embodiments of the claims limited to use of a single primer.

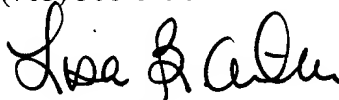
This is a provisional obviousness-type double patenting rejection.

10. No claims are allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa Arthur whose telephone number is (703) 308-3988. The examiner can normally be reached on Monday-Wednesday from 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


LISA B. ARTHUR
PRIMARY EXAMINER
GROUP 1800 1600

August 28, 2000